

In re Application of:
Eric R. CERNY et al.

Serial No.: 10/541,346

Filed: July 5, 2005

Confirmation No.: 8966

**For: COTTON EVENT MON 88913 AND
COMPOSITIONS AND METHODS
FOR DETECTION THEREOF**

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§ Group Art Unit: **1638**
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§ Examiner: **David H. Kruse**
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§ Atty. Dkt. No.: **11899.0239.PCUS00**
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I, Richard D. Voth, declare the following:

1. I earned a doctorate degree in Agronomy from Michigan State University in 1978 and thereafter was employed as a member of the faculty at Louisiana State University for about two years. I have been employed by Monsanto Company since February 25, 1980. Monsanto Company is the parent company wholly owning Monsanto Technology LLC, the assignee of the above-captioned patent application. I have held a number of different positions during my employment with Monsanto Company, including the positions entitled Field Product Development Representative, and Technical Manager for Industrial Turf and Ornamental Products. My present employment position is entitled Cotton Market Development Manager, and

carries with it the responsibility of leading the development of new transgenic traits that Monsanto introduces into cotton. My present position has included being a member of a team with the responsibility for the development of transgenic cotton containing the MON 88913 event, which confers resistance to the herbicide glyphosate. In addition, my responsibilities with respect to developing the MON 88913 event product included acting as the regulatory compliance leader for transgenic cotton during this time frame. A principle role in this position has been to prevent the release of cotton containing the MON 88913 event, except as specified for regulated field evaluation purposes and within Federal, State, and Local Regulated Materials requirements described herein below.

2. I have read, I understand, and I am familiar with the issues with respect to the Request for Information under 37 C.F.R. §1.105 dated January 29, 2007 in the above-captioned application. I also understand that the effective filing date for the above-captioned application corresponds to the February 12, 2003 filing date of Provisional Application S.N. 60/447,184 to which the above-captioned application claims priority, and therefore, that the application's priority date is February 12, 2003. Finally, I understand that any release of the claimed subject matter is only material to the examiner's determination of patentability if such release occurred prior to Feb 12, 2002 (i.e. more than one year before the priority date).

3. As a result of my employment with Monsanto Company and the nexus that my employment positions have had with respect to the development and commercialization of the above-referenced transgenic event MON 88913, it is my opinion that there was no sale or other public distribution of the claimed plant and methods of use thereof anywhere in the United States

or abroad more than one year before the priority date of the above-captioned application based on the following reasoning.

4. Transgenic events are articles restricted from commercialization and therefore are subject to federal regulations, and sometimes state and local regulations, that restrict any intra- or inter-state movement without first obtaining regulatory approvals. Therefore, after insertion of the transgenic events into cotton germplasm, Monsanto Company sought and was provided with regulatory approvals to distribute seeds to various university and field cooperators in geographic regions in the United States where cotton is typically grown commercially. These distributions, which were made under terms of confidentiality and restricted use (refer to below remarks), were approved by all relevant federal regulatory agencies so that Monsanto Company could gather scientific information about the phenotypic characteristics of the transgenic traits corresponding to the regulated transgenic events and compare that information to information gathered in parallel on deregulated transgenic cotton plants and unregulated non-transgenic cotton plants. Therefore, the distribution of the regulated transgenic seed was for the purpose of gathering scientific information, which was experimental in nature, and under tightly controlled conditions approved by certain regulatory authorities. Provided with these seeds were Federal Compliance Packets and Monsanto Company Study Protocols described herein below, which contained provisions restricting the use and movement of such materials, and furthermore restricted the materials from being introduced into any stream of commerce. It is my firm belief that, because of the strict regulatory requirements placed on any movement or field trial of regulated cotton seed containing the MON 88913 event and because of the contractual obligations placed on cooperators outline herein below, no sale, offer for sale, or other activity caused the article to be

publicly available from 2001, when the first field trials of the regulated article were initiated (refer to part 5), through the application's priority date of February 12, 2003.

5. The reference (McCloskey WB, Adu-Tutu KO, Roundup Ready Flex Cotton: Glyphosate Tolerance and Weed Management 2002-2003, *Arizona Cotton Report*, May, 2004, P-138, pp.227-236) cited by the examiner in the above-mentioned Request for Information accurately indicates that cotton containing the MON 88913 event had been released for field trials in the United States in 2002 and 2003. In the cited reference, event 9910 represents the MON 88913 event. For this field trial in Arizona, seeds containing the MON 88913 event were actually first distributed to the study group in April of 2002, which is less than one year before the application's priority date; therefore, this distribution is not material to the examiner's determination. Notwithstanding, it should be understood that this and all other releases made in 2001 and 2002 of regulated seed were made only under the provisions set forth in the Regulatory Compliance Packets provided with each release to a university or field cooperator ("recipient"). These field trial releases were all federally regulated and subjected to strict compliance requirements. Prior to or contemporaneous with the receipt of any regulated seed, each recipient was provided with a Regulatory Compliance Packet and a Study Protocol containing instructions for conducting studies using the regulated transgenic seed. Because the regulated transgenic seeds were restricted articles under USDA regulations, strict compliance with regulatory procedures set forth in the Compliance Packets was required of all recipients. Regulated transgenic seeds were only shipped to a recipient upon receipt by Monsanto of a USDA Interstate Movement and Release Permit.

The Regulatory Compliance Packets that were provided to recipients of the regulated transgenic seed notified each recipient of his or her obligations under federal regulations for such regulated articles, requiring that the recipients restrict access to the seed and materials generated from the seed, restrict movement of the seed or plant materials grown from the seed, maintain the seed and the plots where the seeds were sown under secure conditions, insure that the seed and any plants or produce from the plants be kept from entering into any stream of commerce, isolate fields where the seeds were planted to restrict the movement of pollen to related species, destroy remaining plant material in fields where the seeds were planted, limit replanting in consecutive seasons in the same field and monitor for and destroy volunteer plants that grow in subsequent seasons, and report to Monsanto Company any alterations or deviations from these requirements so that such information reported by a recipient could also be reported to the appropriate federal regulatory authorities requiring such compliance standards. Upon the conclusion of any such regulated field trials, the recipients of such regulated seed were required to execute a statement acknowledging that he/she had received, read, and understood the Monsanto Company and USDA Compliance Packet for each regulated trial being conducted for Monsanto Company and complied with the principles and policies set forth in the USDA Compliance Packet. As certified by each participant, all study groups complied with the agreement standards, including confidentiality restrictions and destruction of all plant and seed materials following the conclusion of the studies. Regulated field trials were conducted by third-party research cooperators in 2001 and 2002 to assess the phenotypic characteristics of cotton containing the MON 88913 event. The trials in 2002 were initiated less than one year before the application's priority date so are not material to the examiner's determination but are included herein for reference.

<u>Location</u>	<u>Cooperator</u>	<u>Institution</u>	<u>Year Tested</u>
Belle Mina, AL	Charlie Burmester	Auburn University	2001
Florence, SC	Mike Jones	Clemson University	2001
Keiser, AR	Fred Bourland	University of Arkansas	2001
Maricopa, AZ	Bill McCloskey	University of Arizona	2001
Starkville, MS	Johnie Jenkins	Mississippi State University	2001
Tifton, GA	Lloyd May	University of Georgia	2001
Belle Mina, AL	Mike Patterson	Auburn University	2001
Clayton, NC	Alan York	North Carolina State University	2001
College Station, TX	Tom Cothren	Texas A&M University	2001
Jackson, TN	Bob Hayes	University of Tennessee	2001
Starkville, MS	Dan Reynolds	Mississippi State University	2001
Alexandria, LA	Roy Vidrine	Louisiana State University	2002
Belle Mina, AL	Mike Patterson	Auburn University	2002
College Station, TX	Tom Cothren	Texas A&M University	2002
Jackson, TN	Bob Hayes	University of Tennessee	2002
Keiser, AR	Chris Tingle	University of Arkansas	2002
Lubbock, TX	Wayne Keeling	Texas A&M University	2002
Maricopa, AZ	Bill McCloskey	University of Arizona	2002
Nichols, SC	Ed Murdoch	Clemson University	2002
Portland Texas	Sid Hopkins	Hopkins Agricultural Services	2002
Clayton, NC	Alan York	North Carolina State University	2002
Rowher, AR	Ken Smith	University of Arkansas	2002
Tifton, GA	Lloyd May	University of Georgia	2002
Vernon, TX	Todd Baughman	Texas A&M University	2002
Alexandria, LA	Sandy Stewart	Louisiana State University	2002
Belle Mina, AL	Charlie Burmester	Auburn University	2002
Florence, SC	Mike Jones	Clemson University	2002
Maricopa, AZ	Jay Subramani	University of Arizona	2002
Portageville, MO	Bobby Phipps	University of Missouri	2002
Rocky Mount, NC	Keith Edmisten	North Carolina State University	2002
Starkville, MS	Johnie Jenkins	Mississippi State University	2002

Each Study Protocol, which was part of an executed contract between Monsanto and the recipient, provided the following notice to the recipient of the regulated seeds:

All information regarding the identity of the test substance(s), associated samples, and data must be kept strictly confidential. No raw data, worksheets, observations, data or information summaries, reports, or other information related to this study may be revealed or released to any third party without prior notification and authorization of Monsanto Company.

Furthermore, the executed contract (Memorandum of Agreement) between Monsanto and the study cooperator outlined the confidential nature of the field study and provided restrictions on any unauthorized distribution of the seed, including the following restriction:

You acknowledge that seed provided by Monsanto for the trial is the confidential material of Monsanto and agree not to pass such seed to any party not authorized by Monsanto in writing prior to such transfer.

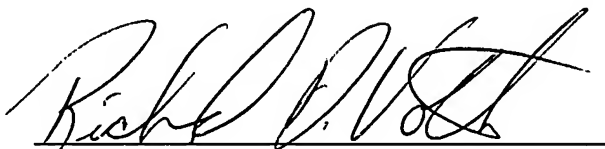
To my knowledge no unauthorized transfer of seed occurred.

6. The Examiner has also requested information about ex-US distributions. To my knowledge, the only *third-party* distributions made by Monsanto outside of the US occurred after February 12, 2003 (i.e. the application's priority date). The only actual shipment of seeds containing the MON 88913 event outside the US before the application's priority date was made internally to Monsanto personnel in Australia on December 18, 2002, which was less than one year before the application's priority date. In connection with this particular shipment, MON 88913 event-containing seeds were later provided after the application's priority date to the Commonwealth Scientific and Industrial Research Organization (CSIRO), which is the Australian equivalent of the USDA, on February 18, 2003 (ten seeds) and March 10, 2003 (twenty-four seeds) for the purpose of initiating a variety development program with elite germplasm from the CSIRO, per a license from Monsanto.

7. Therefore, based on my experience with this transgenic event and its development, the regulatory approval process through which the event traversed, its commercialization history, and the facts that I declare herein above, it is my opinion that no sale or offer for sale of the MON

88913 transgenic cotton event was made more than one year before the priority date of the instant application, and that there was no public use of this material more than one year before the priority date of the instant application.

8. I hereby declare that all statements made herein above are of my own knowledge and are true, and that all statements are made on information believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

A handwritten signature in dark ink, appearing to read "Richard D. Voth", is written over a horizontal line.

Richard D Voth, Ph.D.
Monsanto Company, E3NA
800 North Lindbergh Blvd.
St. Louis, MO 63167

Date: 6/1/2007